Study: CDISCPILOT01 Page 1 of 2
Subject: 01-701-1111 (1111) First Dose Date: 2012-09-07
Status: ADVERSE EVENT Current Visit: RETRIEVAL

Demographics										
Country Age (y) Sex Race		Ethnicity	Planned Arm	Actual Arm						
USA	81	F	WHITE	NOT HISPANIC OR LATINO	Xanomeline Low Dose	Xanomeline Low Dose				

Subject Visits							
Visit	Visit Day	Visit Date					
SCREENING 1	-7	2012-08-25					
SCREENING 2	-1	2012-09-05					
BASELINE	1	2012-09-07					
WEEK 2	14	2012-09-17					
AE FOLLOW-UP		2012-09-29					
RETRIEVAL	168	2013-02-22					

Adverse Events									
Sponsor Defined Identifier and Verbatim Term	Start Date (Day)	End Date (Day)	Ser-ious?	Dur- ation (days)	Sever- ity	Relation- ship	Outcome	Action Taken	Treatment Emergent?
E06: LOCALISED INFECTION	2012-07-08 (-61)		No		Moderate	None	Not Recovered/Not Resolved		No
E14: ERYTHEMA	2012-09-02 (-5)	2012-09-07 (1)	No	7	Mild	None	Not Recovered/Not Resolved		No
E14: ERYTHEMA	2012-09-02 (-5)	2012-09-07	No	7	Mild	None	Recovered/Resolved		No
E15: PRURITUS	2012-09-02 (-5)	2012-09-07	No	7	Mild	None	Not Recovered/Not Resolved		No
E15: PRURITUS	2012-09-02 (-5)	2012-09-07 (1)	No	7	Mild	None	Recovered/Resolved		No
E16: ARTHRALGIA	2012-09-13 (7)		No		Moderate	None	Not Recovered/Not Resolved		Yes
E17: CELLULITIS	2012-09-13 (7)		No		Moderate	None	Not Recovered/Not Resolved		Yes
E18: MICTURITION URGENCY	2012-09-07 (1)		No		Mild	None	Not Recovered/Not Resolved		Yes

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Vital Signs								
Vital Sign Parameter	SCR1	SCR2	BSLN	WK02	RETR			
Diastolic BP (mmHg)	65	74	71	60	64			
Pulse Rate (BEATS/MIN)	84	89	85	84	74			
Systolic BP (mmHg)	122	129	135	110	130			
Temperature (C)	37	36.6	36.7	37.1	36.5			
Weight (kg)	60.3		59.9	60.8	•			

